



Roy Zimmerman, Director  
Office of Nuclear Security and Incident Response  
US NRC MS T-4D22A  
Washington, D.C. 20555

FEB 15 2007

Reference Number: OGD #07-0163

Dear Mr. Zimmerman:

This is in response to a February 5, 2007 e-mail request and other e-mail exchanges from Patricia Milligan, Senior Advisor for Emergency Preparedness, US Nuclear Regulatory Commission. The communications were regarding the appropriateness of the States that had obtained Iosat® Tablets (Potassium Iodide Tablets, USP) extending the expiration dating period of these stockpiled lots to 7 years.

We understand that certain state governments have received from the Nuclear Regulatory Commission (NRC) Iosat® Tablets (Potassium Iodide Tablets USP) manufactured by Anbex, Inc. for stockpiling in the event of a radiation emergency. This drug product is manufactured under the approved Abbreviated New Drug Application (ANDA) 18-664. We understand that the stockpiled lots bear a 5 year expiration dating period. As it is known to the NRC that Anbex, Inc. has received approval from the Office of Generic Drugs (OGD) to apply a 7 year expiration dating period to this drug product, NRC requests advice from FDA as to whether it would be appropriate for the stockpiled lots that have a 5 year expiration date to have the expiration extended another 2 years.

When the expiration dating period of a drug product that is subject to an ANDA is extended by the manufacturer either due to FDA approval or under a protocol that had been approved by FDA, the extended expiration dating period is considered to apply to new lots manufactured after the extended expiration dating period has been implemented. The FDA does not have any regulation or policy regarding the application of an extended expiration dating period to lots that were manufactured prior to the implementation of the extended expiration dating period. However, FDA does not object to such a practice as long as adequate records are kept and doing so is scientifically sound. It would be considered to be scientifically sound if the lots having the expiration date extended had no significant difference in formulation, manufacturing process or packaging materials from current lots. The letter to Patricia Milligan at NRC from counsel to Anbex, Inc. dated January 23, 2007 indicates that this is the case.

Given the above information, it is our opinion that it would be scientifically valid and, therefore, appropriate for the stockpiled lots of Iosat® Tablets to have their expiration date extended by an additional 2 years. The States should ensure that the lots have been properly stored as recommended on the drug product label and also maintain an adequate record of the expiration date extension. This opinion is based strictly on scientific considerations. Any issues related to contractual agreements between the parties are outside the scope of these comments.

If you have any additional questions, please contact Mr. Michael Smela at 301-827-5775.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary Buehler", with a stylized, cursive script.

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

Via e-mail to: [rpz@nrc.gov](mailto:rpz@nrc.gov)  
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